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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,099	08/08/2001	Yoshihiro Nishida	NISHIDA=3A	3370

7590

07/28/2005

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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

*he*

## Office Action Summary

Application No.

09/924,099

Applicant(s)

NISHIDA ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED OFFICE ACTION**

The request filed on 31 May 2005 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/924,099 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 20 May 2005 is acknowledged and entered. Following the amendment, claims 47-50 are amended.

Currently, claims 47-54 are pending and under consideration.

#### **Withdrawal of Objections and Rejections:**

The new matter rejection of claims 47-54 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendment.

The rejection of claims 47-54 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

#### **Rejections Over Prior Art:**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 47-54 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Taniguchi et al. (J Immunol. Methods, 1997, 206: 107-113), in view of Kohno et al. (Clin. Immunol. Immunopath., January 1998, 86(1): 11-15), and Riechmann et al. (Nature, 1988, 332:323-327), for the reasons of record set forth in the previous Office Actions mailed on 27 August 2003, 07 April 2004, and 30 November 2004.

Applicants argument filed on 20 May 2005 has been fully considered, but is not deemed persuasive for reasons below.

At pages 6-11 of the response, the applicant argues that the combination of Taniguchi and Kohno does not give a “reasonable expectation” of success, that the examiner has failed to point to any evidence in the cited references that would motivate or suggest that an antibody to IL-18 can be used to treat RA and arrive at the present invention, and therefore, there is no prima facie case of obviousness. This argument is not persuasive because, besides RA, the present claims also encompass “inflammatory diseases”, and as addressed in the previous Office Actions, Kohno teaches, in addition to the potential use of anti-IL-18 antibody for the treatment of RA, that administration of anti-IL-18 antibodies completely reversed the endotoxin-induced fluminant hepatitis, which is an “inflammatory disease” (as recited in the present claims), and meets the limitation in the present claims. Such teachings are beyond “a reasonable expectation” of success as the result confirms the therapeutic effect of anti-IL-18 antibody treatment on an inflammatory disease.

**Conclusion:**

No claim is allowed.


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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
7/12/05

  
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